

## **REMARKS**

### **I. INTRODUCTION**

Claims 51-72 are currently pending in the present application. In view of the following remarks, Applicant respectfully submits that the pending claims are now in condition for allowance.

### **II. REJECTIONS UNDER 35 U.S.C. § 102(b)**

Claims 51-64 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Doyle *et al.* (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00). For at least the following reasons, Applicant respectfully submits that Doyle *et al.* does not disclose the claimed patient populations, and thus does not anticipate the pending claims.

To anticipate a claim, a reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Furthermore, “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted) (emphasis added); *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (CAFC reversed obviousness rejection because inherency was based on “optimal” conditions, and the means for achieving such “optimal” conditions were not explicitly or implicitly disclosed in prior art); M.P.E.P. § 2112, IV. Thus, the

M.P.E.P. and the case law make clear that simply because a certain result or characteristic *may* occur in the prior art does not establish the inherency of that result or characteristic.

The method of the present invention, as currently recited in independent claim 51, is directed to a mammal that is “asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in said mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Claims 52-56 and 63 ultimately depend from claim 51 and thus include this limitation as well. Similarly, the method of the present invention, as currently recited in independent claim 57, is directed to a mammal that is “asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in said mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Claims 58-62 and 64 ultimately depend from claim 57 and thus include this limitation as well. That is, the methods of the pending claims do not cover just any mammal, but only those specifically recited mammals as articulated in the claims.

In the Office Action dated April 30, 2009, it states that “[n]o evidence of cardiorespiratory disease necessarily includes patient populations that are asymptomatic to lung damage or alveolo-capillary membrane damage without invasive procedures because they have *no evidence of cardiorespiratory disease*.” (Office Action dated April 30, 2009, page 3 (emphasis in original)). Similarly, in the previous Office Action dated July 3, 2008, it states that “Doyle *et al.* compares OD (without evidence of cardiorespiratory disease) to normal levels. As such, they necessarily and inherently compared asymptomatic (i.e. without evidence of cardiorespiratory disease to normals).” (Office Action dated July 3, 2008, page 4). Applicant respectfully disagrees with these statements, and submits that Doyle *et al.* does not disclose or suggest the claimed patient populations.

In support of this position, Applicant submits herewith a Declaration under 37 C.F.R. § 1.132 of Dr. Guy Marks. As stated in the Declaration of Dr. Marks, upon reading Doyle *et al.*, one of ordinary skill in the art could not definitively determine the precise physical characteristics of the individuals in the normal group or OD group disclosed therein. That is, one of ordinary skill in the art could not determine with certainty that a member of the normal group or OD group disclosed therein is necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or necessarily of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.”

Therefore, for at least the preceding reasons, it is respectfully submitted that the rejections under 35 U.S.C. § 102(b) have been overcome and should therefore be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 51-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Doyle *et al.* (Am. J. Respir. Crit. Care Med. 1994; 149; A576) (“Doyle A”) in view of Doyle *et al.* (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00) (“Doyle B”), Doyle *et al.* (Am. J. Respir. Crit. Care Med. 152:307-317, 1995) (“Doyle C”), Honda (Japanese Journal of Thoracic Diseases, 34 Suppl Abstract only, December 1996; reference A11 on PTOL-1449 of 6/6/00) and Abe *et al.* (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6/6/00). Applicant respectfully submits that these rejections should be withdrawn for at least the following reasons.

As described above in regard to the anticipation rejections, Doyle B does not disclose the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims 51-56, 63 and 65-68. Likewise, Doyle B does not disclose the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims 57-62, 64 and 69-72.

Neither Doyle A, Doyle C, Honda nor Abe *et al.* cure the shortcomings of Doyle B. That is, neither Doyle A, Doyle C, Honda nor Abe *et al.* disclose or suggest that the individuals therein are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.”

Thus, for at least the preceding reasons it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

IV. CONCLUSION

In view of the foregoing, Applicant respectfully submits that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,  
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